HORIZON 2020
The EU Framework Programme for Research and Innovation

CAPABLE

Cancer Patients Better Life Experience

Grant Agreement No. 875052
Start Date: 01/01/2020 (48 Months)

Deliverable No. 8.6
Intellectual Property report – V2

Due Date: [31/1/2024]
Submitted On: [02/4/2024]

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Deliverable Type		
R	Document, report	**[X]**
DEM	Demonstrator, pilot, prototype	
DEC	Websites, patent fillings, videos etc.	
OTHER		
Dissemination Level		
PU	Public	**[X]**
CO	Confidential (Consortium members including the Commission Services)	
CI	Classified Information (Commission Decision 2015/444/EC)	

This deliverable is a part of a project receiving funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875052.

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Versions History

Version	Date	Author	Comments
1.0	15th November 2023	UPM	Table of Content
1.0	25 March 2024	UPM	Final version

1.Executive Summary

Deliverable 8.6 presents the activities related to the Intellectual Property (IP) Management for the CAPABLE project. The report presents the overall progress of management of the IP and it presents the foreground assets classified in software, data, and knowledge results. Finally, the document presents the IP procedures that will be taken to monitor, assess and protect the results beyond the project's timeline.

2.Management of IP

This deliverable provides the final updates on the management procedures of the Intellectual Property for the CAPABLE project, that have been previously reported in D8.3 (at month 24) and in D8.5 (at month 36, see section 5.2).
As for previous deliverables, also the present one relies on the legal basis provided in the Consortium Agreement rather like the Grant Agreement.
In the past months a proper IP management structure has been implemented to encompass four fundamental dimensions:

- Assets Management: Aligned with the General Assembly document on ownership, this involves determining ownership rights and access privileges for results and background information.
- Assets Protection: This refers to the pursuit of optimal strategies for safeguarding intellectual property.
- Assets Valorization: This focuses on articulating a strategic portfolio for exploitation, along with a communication strategy and result portfolio for the CAPABLE project.
- IP Procedures: This entails delineating roles, responsibilities, and procedures for monitoring intellectual property activities throughout and post the project duration.

The IP management activities focused on three types of assets that will be presented in the next sections: software, data and knowledge assets.

Software assets

The software assets represent the essential components of the CAPABLE system architecture. Each identifiable software asset has been detailed in the IPR Identification Sheet, taking into account the following dimensions:

- Name of the exploitable software.
- Description of the result.
- Ownership, intended as Partner(s) that generate the software asset.
- Background underlying assets (if any), namely background item(s) on which the software asset is built upon.
- Other underlying assets (if any), non-background item(s) on which the software asset is built upon.
- IP condition, e.g., proprietary, FOSS (Free Open Source Software).
- License, e.g., copyright, Apache License Version 2.0, BSD, MIT X11.
- Public availability of the result, e.g., no, only demo, GitHub, SourceForge.

The next table provides the reader the overall summary of the CAPABLE software assets.

System	Description	Owners
CAPABLE system	Telehealth system for cancer patients during treatment.	UNIPV, DEON, PUT, UoH, BIT, BIOM and PUT (14,2% each)
Multimorbidity Controller (GoCom) - UoH	The Multimorbidity Controller (GoCom) will receive information from the guidelines after they have completed a run and check for interactions between the guideline recommendations and the patient's existing medications.	UoH

Physician Decision Support Component (Physician DSS / PDSS).	Physician DSS is an adaptor component that interfaces the Deontics Computer.Interpretable Guidelines engine to the CAPABLE system.	DEON
Deontics Engine	Engine used by PDSS, VC and GoCom components to execute PROforma CIGs	DEON
Predictive models and tools (risk prediction and disease progression) as well as statistical models for sensors data	Accurate data-driven prediction models and statistical models that provide an aggregated prediction for patients outcome given their current state, past history and potential interventions. Also, tools to create the models such as FuseMedML open source and CausalLib open source.	IBM
Natural Language Processing algorithm	This algorithm is used to collect a rich set of patient related data including unstructured information in the form of text, such as from patients' and caregivers' forums, potentially mails and communication inside the system	UniPV 90%; AIMAC 10%
Virtual Coach	Virtual Coach acts as the "execution environment" for PROforma CIGs (result in row 14) that implement the domain knowledge model (result in row 13). VC interacts with other components of the CAPABLE system -- in particular it employs the Deontics Engine (DE) to execute CIGs and it communicates with the users via Patient and Physician Apps. It also relies on services provided by CM and DP.	PUT
Care provider (Clinicians) dashboard	Web app developed to dynamically configure the patient application the information provided to the patient and manage patient data by clinicians.	BIT
Patients & caregivers mobile app, Doctors web dashboard	Mobile app to allow their disease management, including functionalities such as, record their symptoms, management personal data and care plans, receive coaching advice, alerts and recommendations; and communicate with the care provider. Doctors web dashboard to allow doctors track patients activity, and to see in the dashboard what is happening in the app.	BIT
(KDOM)Ontology based knowledge - data mapper	The Knowledge-Data Ontology Mapper (KDOM), is a tool that allows mapping different schemas of knowledge and data to each other.	UoH

Data Platform	CAPABLE data platform aims at storing all the data that are relevant for the project (coming both from the EHR and generated within the project context). The persistence layer is constituted by an extended version of the OMOP Common Data Model.	BIOM
Case Manager	The Case Manager is the component responsible for driving the reasoning process within the system. The approach adopted by CAPABLE is based on the advertisement of Events: each component hosting a Knowledge Source specifies a set of Events in terms of a combination of facts about the patient.	UNIPV
Knowledge model (used by VC) related to virtual capsules, rewards and motivational messages	The knowledge model covering: (1) ontology of wellbeing goals and virtual capsules and specification of the capsules related to evidence based recommendations behind the capsule activity, to its properties related to Fogg's behavioral model (2) repository of motivational messages for My Usual Walk capsule and strategy of defining a sequence of messages for a given patient (3) repository of rewards (badges and medals) related to virtual capsules and definition of rules controlling the assignment of rewards (4) structure of relevant FHIR resources (Observation, Communication) to store interventions and rewards	1/3 each for UNIPV, PUT, UoH
PROforma CIGs (used by VC) implementing clinical and non-clinical workflows and rules, including patient-oriented parts of clinical guidelines	PROforma CIGs implementing workflows and clinical rules used by VC. These CIGs are representation-specific implementation of the knowledge model and include: (1) patient-specific clinical guidelines (2) administrative workflows and rules for administering questionnaires (3) workflows for various types of tips (preventive, supportive) and reminders (visits, symptom reports, hobbies) (4) workflows for My Usual Walk motivational support (5) rules for assigning rewards	1/3 each for UNIPV, PUT, UoH

The assets have been established, and the relevant dependencies with the background have been acknowledged. Each software asset's intellectual property condition, access level, and fee model have been clearly outlined. This information underwent periodic review every six months. The following tables provide the final comprehensive details of the assets.

Component Name/Result	CAPABLE system

Ownership	The ownership is equally distributed between the technical partners that produced the components and correspond to 14,2% between UNIPV, DEON, PUT, UoH BIT, BIOM and PUT.
Background underlying assets	This asset is the result of the integration of other assets.See other assets backgrounds.
IP Condition	Proprietary
Differences between context of commercial and no commercial purpose (Differences)	Dissemination: all the Consortium partners have access to a demo server of the CAPABLE technology and can create temporary accounts (duration max 1 month) for 3rd parties to evaluate the technology. Evaluation: a 3rd party will access (temporarily) to the service to evaluate patient app and clinical dashboard Clinical use and other uses: they will be considered commercial use and a specific agreement must be signed and a fee would be applied.
Specify level of access	Access to CAPABLE service
Model of fee	Annual fee to sustain maintenance, compliance and system improvement. Additional costs for service deployments, service personalization, integration with EHR
Public availability	Available for demonstration at https://capable-project.eu/demo/ Potential use in further clinical settings will be negotiated by UPM and UNIPV.

Component Name/Result	Multimorbidity Controller (GoCom)
Ownership	UoH
Background underlying assets	Previous publications in scientific journal on Go Comm component
IP Condition	Proprietary
Differences between context of commercial and no commercial purpose (Differences)	No difference
Specify level of access	API
Model of fee	Perpetual
Public availability	No. Available for demonstration

Component Name / Result	Physician Decision Support Component (Physician DSS / PDSS)
Ownership	DEON
Background underlying assets	PDSS uses the Deontics Runtime Engine API (DRE API) to interface to the Deontics DSS Engine service, as do some other components (GoCom, VC)
IP Condition	Proprietary
Differences	No difference is expected
Specify level of access	API
Model of fee	Annual license
Public availability	Yes

Component Name / Result	Deontics Engine

Ownership	DEON
Background underlying assets	Deontics Runtime Engine
IP Condition	Proprietary
Differences	No difference is expected
Specify level of access	API
Model of fee	Annual license
Public availability	No. Available for demonstration

Component Name / Result	Predictive models and tools (risk prediction and disease progression) as well as statistical models for sensors data
Ownership	IBM
Background underlying assets	No
IP Condition	Proprietary, the tools to build the models are freely accessible: FuseMedML is open source and CausalLib is open source.
Differences	No
Specify level of access	API
Model of fee	No
Public availability	No

Component Name/Result	Natural Language Processing algorithm
Short description	This algorithm is used to analyze a rich set of patient related unstructured data in the form of text, such as from patients' and caregivers' forums, potentially mails and communication inside the system.
Ownership	UniPV 90%; AIMAC 10%
Background underlying assets	Expertise in NLP applied to clinical text reports Natalia Viani, Timothy A. Miller, Carlo Napolitano, Silvia G. Priori, Guergana K. Savova, Riccardo Bellazzi, Lucia Sacchi, Supervised methods to extract clinical events from cardiology reports in Italian, Journal of Biomedical Informatics, Volume 95, 2019 Viani N, Larizza C, Tibollo V, Napolitano C, Priori SG, Bellazzi R, Sacchi L. Information extraction from Italian medical reports: An ontology-driven approach. Int J Med Inform. 2018 Mar;111:140-148. doi: 10.1016/j.ijmedinf.2017.12.013. Epub 2017 Dec 23. PMID: 29425625. E. Parimbelli, S. Quaglini, C. Napolitano, S. Priori, R. Bellazzi, and J. H. Holmes, "Use of Patient Generated Data from Social Media and Collaborative Filtering for Preferences Elicitation in Shared Decision Making," in AAAI Fall Symposium Series, 2014
IP Condition	OpenSource
Differences	N/A
Specify level of access	API and source code

Model of fee	None
Public availability	Yes

Component Name/Result	Virtual Coaching system
Ownership	PUT
Background underlying assets	(1) Know-how on designing and implementing workflow-driven multi-agent clinical decision support systems (2) Prototype solutions from earlier research (3) Publications: * Sz. Wilk, M. Kezadri-Hamiaz, D. Amyot, W. Michalowski, C. Kuziemsky, N. Catal, D. Rosu, M. Carrier, R. Giffen, An Ontology-driven Framework to Support the Dynamic Formation of an Interdisciplinary Healthcare Team, International Journal of Medical Informatics 136 (2020) 104075. * D. Astaraky, Sz. Wilk, W. Michalowski, P. Andreev, C. Kuziemsky, S. Hadjiyannakis, Supporting an Interdisciplinary Healthcare Team with a Multi-Agent System, in: M. Cruz-Cunha, I. Miranda, R. Martinho, R. Rijo (Eds.), Encyclopedia of E-Health and Telemedicine, IGI Global, 2016, pp. 371-382. * Sz. Wilk, D. O'Sullivan, M. Kezadri-Hamiaz, C. Kuziemsky, D. Rosu, W. Michalowski, M. Fung-Kee-Fung, Aligning Interdisciplinary Healthcare Team Behavior with Workflow Execution: An Example of a Radical Prostatectomy Workflow, in: 2016 IEEE 29th International Symposium on Computer-Based Medical Systems (CBMS), IEEE, 2016, pp. 112-117.
IP Condition	Open source
Differences	Additional services available commercially (e.g., customization for specific conditions, like other CIG execution engine)
Specify level of access	1) Source code 2) Access throughout the CAPABLE demo
Model of fee	None
Public availability	Yes. https://github.com/capable-project/capable-vc

Component Name/Result	Care provider (Clinicians) dashboard.
Ownership	BIT
Background underlying assets	No
IP Condition	Proprietary
Differences	In a non-commercial setting the system can be used for demonstration purposes and/or research without alteration of its source code (except for bug corrections that should be reported to BIT). It should not be used in real life set-up nor to be sold or access-given to third parties.
Specify level of access	Web access
Model of fee	N/A
Public availability	Only demo

Component Name/Result	Patients & caregivers mobile app

Short description	Mobile app to allow their disease management, including functionalities such as, record their symptoms, management personal data and care plans, receive coaching advice, alerts and recommendations; and communicate with the care provider.
Ownership	BIT
Background underlying assets	No
IP Condition	Proprietary
Differences	In a non-commercial setting the system can be used for demonstration purposes and/or research without alteration of its source code (except for bug corrections that should be reported to BIT). It should not be used in real life set-up nor to be sold or access-given to third parties.
Specify level of access	App
Model of fee	Perpetual license per installation on a mobile device, with an option to renew fees every year.
Public availability	Demo video.

Component Name / Result	(KDOM)Ontology-based knowledge-data mapper
Ownership	UoH
Background underlying assets	Preexisting result, expanded in the CAPABLE research: Peleg M, Keren S, Denekamp Y. Mapping computerized clinical guidelines to electronic medical records: Knowledge-data ontological mapper (KDOM). Journal of biomedical informatics. 2008 Feb 1;41(1):180-201.
IP Condition	Proprietary
Differences	No difference
Specify level of access	API
Model of fee	Perpetual
Public availability	No. Available for demonstration

Component Name / Result	Data Platform
Ownership	BIOM
Background underlying assets	Background for DP is the OMOPonFHIR open-source project, which DP constitutes a fork of.
IP Condition	OpenSource
Differences	No
Specify level of access	Source code
Model of fee	No
Public availability	Yes. The publication is ongoing because it requires a process of refactoring and generalization.

Component Name / Result	Case Manager
Ownership	UNIPV
Background underlying assets	No
IP Condition	Proprietary
Differences	No
Specify level of access	API
Model of fee	Perpetual license
Public availability	No. Available for demonstration

Component Name / Result	Knowledge model (used by Virtual Coach) related to virtual capsules, rewards and motivational messages
Ownership	UNIPV, PUT, UoH (33,3% each)
Background underlying assets	Yes, existing previous works on methods extending the system development life cycle with a stage that realizes psychobehavioral techniques as concrete digital behavioral change interventions (DBCIs). https://doi.org/10.1007/s10916-018-1077-4 and https://norma.ncirl.ie/id/eprint/3154
IP Condition	Open source
Differences	commercial consulting services (e.g., customizing capsules to specific conditions, adding new capsules on request, revising or adding rewards, implementing the model using other CIG representation)
Specify level of access	knowledge repo (no "typical" source code) - ontology
Model of fee	No
Public availability	Publication: DOI: 10.1016/j.jbi.2022.104276 Link to the ontology in Bioportal: https://bioportal.bioontology.org/ontologies/SATO

Component Name / Result	PROforma Computer Interpretable Guidelines (CIGs) (used by VC) implementing clinical and non-clinical workflows and rules, including patient-oriented parts of clinical guidelines
Ownership	UNIPV, PUT, UoH (33,3% each)
Background underlying assets	No
IP Condition	open source
Differences	commercial consulting services (e.g., revising CIGs, adding CIGs for new workflows)
Specify level of access	1) Code 2) Access to the service throughout the CAPABLE demo
Model of fee	No
Public availability	Yes, https://github.com/capable-project/capable-vc-cig

Data assets

The results (such as data, knowledge or information) of the CAPABLE project are those generated from the Consortium Partners within the action. According to art. 26 of the Grant Agreement, results are owned by the partner/s that has generated them. In case results are generated by more than a partner and it is not possible to establish the single partner contribution or to separate them for the purpose of applying for, obtaining or maintaining their protection, the partners own the results jointly (joint ownership), under an agreement that they have been asked to set up. Partners obtain all the necessary rights in case results are generated by third parties.
Data assets in the project refer to the data generated or processed, and they are characterized by specific metrics:

- Dataset Name: Identifies the particular dataset.
- Data Description: Provides an overview of the data content and purpose.
- Ownership: Specifies the partner or partners responsible for generating the result.
- Underlying Background and Assets: Describes the context or dependencies related to the data asset.
- Data Type: Indicates whether it is a dataset or a data model.
- Format: Specifies the supported formats of the datasets.
- License: Defines the type of license governing the data's use.
- Privacy Level: Indicates the sensitivity of information in the dataset that may require protection.
- Confidentiality Level: Specifies whether the data asset is accessible and outlines measures to protect confidentiality.

Name of the data-set	Description	OWNERSHIP	Background underlying data assets	Data type	Format	License	Privacy level	Confidentiality level
Patient raw dataset	Data extracted from the EHR at the hospitals.	ICSM, NKI	For ICSM and NKI: The data is intended for the only use in the project .	dataset	CSV	NO	Data are pseudo-anonymized	Cannot be shared for both NKI and ICSM

Patients CAPABLE dataset	New data generated by the CAPABLE system. Data collected through questionnaires, wearable or environmental sensors located at the patient home, during the execution of the CAPABLE project.	ICSM, NKI	For NKI: The data is intended for the only use in the project .	dataset	CSV	YES	Data are pseudonymized	Accessible under request through Zenodo an anonymized and aggregate version of the dataset
UX studies data sets	New data generated during the User Experience studies. Data are formed by qualitative and quantitative study. According to the study protocol and informed consent data are anonymized	ICSM, NKI	For NKI: The data is intended for the only use in the project .	dataset	Excel format	No	Data are anonymized	Data will be stored by ICSM, NKI, UPM, UNIPV

CAPABLE extended OMOP Data model	OMOP CDM is a structure for representing data plus a set of vocabularies to describe them. For CAPABLE scope it has been extended by BIOM	BIOM	OMOP CDM	Datamodel	SQL Database + Data	Open-source	N/A, no data inside the data model	Public
CAPABLE Catalogue (Fair Data Point)	Metadata catalog of Computer- and Human-Interpretable Guidelines	AMC, UNIPV, DEON, UOH	No	DCAT-compliant Metadata	Turtle	cc-by-nc-nd3.0	N/A	Open access: https://w3id.org/CAPABLE/fdp-catalog

Knowledge

The CAPABLE project has been a unique experience to generate and consolidate knowledge in different domains that are presented in the following table.

Partners	Domain	Knowledge description
UNIPV, UoH, DEON, PUT, AMC	Computer models	modeling clinical practice guidelines (CPGs), rules and workflows using formal representations (PROforma), modeling additional domain knowledge in form of ontological models expressed in the OWL language
AMC, UNIPV, BIOMERIS	Information modeling/system interoperability	identification and configuration of FHIR resources
UoH, AMC	System requirements	definition of user needs
PUT	Software design and development	designing complex software systems (e.g., employing multi-agent or actor-model paradigm) and their implementation using modern technologies
BIOMERIS	Data integration	Harmonize separate data sources towards a data model and make them available for secondary use
	Software design & development	Develop new software
ICSM, NKI, UNIPV, AMC,	Study design	definition of study protocols for control cohort
ICSM, NKI, UNIPV, AMC, UPM	Study design	definition of study protocols for study cohort
UPM,ICSM, NKI, UNIPV, AMC	Study design	definition of study protocols for user experience evaluation
ICSM, BIOMERIS,NKI,UNIPV	System deployment	existing environments in the two hospitals
UNIPV, ICSM, NKI, UoH, PUT, DEON, AMC	System evaluation	Knowledge validation
IBM, PUT	Machine Learning	developing predictive models for patients' outcomes, application of simulation and machine learning (including reinforcement learning) to construct models for adjusting well being activity prompts sent to patients; Developing predictive models using Machine Learning and Deep Learning methods for prediction of treatment outcomes; Developing tools for explainability of these models.
PUT	Wearable sensors	developing software solutions for communicating with wearable devices (smartwatches) and data platforms dedicated for these devices (in particular ASUS VivoWatch smartwatches and the OmniCare platform), processing of data extracted from sensors

		(e.g., calculating abstractions, identifying predefined patterns)
UPM, BIT, DEON	Exploitation and business strategy in digital health	Knowledge on market of digital therapeutics in oncology, business models and exploitation strategy
BITSENS	UI & UX design, development and deployment	Improving UX based on advanced prototyping, mobile apps

It is notable to mention that, as part of the knowledge, the project produced a set of deliverables that have been published in Zenodo (https://zenodo.org/communities/capable) and in the project Webpage using the Creative Commons license. These documents are the following:

- D1.2: Data Management Plan
- D2.1: Requirements Table and Use Case Description
- D2.2: Requirements Table and Use Case Description
- D3.1: Information Architecture
- D3.2: Data-related Functionality to Realize a FAIR Infrastructure
- D3.3: Specification of the Information Architecture and Data Modeling Based on FAIR Principles
- D3.4: Computer-Interpretable Guidelines
- D4.1: 1st Iteration of the Platform Proof Of Concept
- D4.2: 2nd iteration of the Platform Proof of Concept
- D4.3: Final Iteration of the Platform Proof of Concept
- D4.4: Final Platform Version and Deployment on all the Clinical Sites Involved
- D5.1: Data Ready for Modelling and Reasoning Development
- D5.2: Framework Defined (Including Patients' Needs) Based on Available Data and Modelling Approaches
- D5.3: Prototype of Guideline-based Decision Component
- D5.4: Prototype of Statistical-based Decision Component
- D5.5: Prototype of the Coaching System with Selected Representative Interventions
- D5.6: Prototype of Backend DSS, Ready for Integration with the Pilot System
- D5.7: Refined Framework and Models of All Prototypes Based on Accumulated Data
- D6.2: User Interfaces Prototype 1
- D6.3: User Interfaces Prototype 2
- D7.1: Study Plan, Protocols Definition, and Informed Consent/Assent Drafts
- D7.2: AI Ethics and Incidental Findings Policy
- D7.3: First Interim Usability and Acceptability Evaluation Report
- D7.4: Second Interim Usability and Acceptability Evaluation Report
- D7.5: Third Interim Usability and Acceptability Evaluation Report
- D7.6: Informed Patient Consent/Assent Form, Ethical Committee Approval, Training Materials, and Technical Manual for Maintenance
- D7.7: Interim Report on System Performances, Usage and Technical Improvements
- D8.1: Market Opportunity Report
- D8.2: Market Analysis V2
- D8.3: Intellectual Property Report V1
- D8.4: Exploitation Plan and Business Models V1
- D8.5: Exploitation Plan and Business Models – V2
- D9.1: Project Logo, Leaflets, Presentation and Website

- D9.2: Dissemination Activities Report – Part 1

IP procedures beyond the project

Intellectual Property (IP) procedures extending beyond the project involve the establishment of protocols and guidelines to govern the management and protection of intellectual property assets after the project's conclusion. These procedures encompass:

Continued Monitoring: Implementing mechanisms to monitor and assess intellectual property activities post-project, ensuring ongoing compliance with established protocols.
After the project every partner will be responsible to monitor their own results and the overall CAPABLE system will be monitored by the coordination team (UNIPV) and by the exploitation manager (UPM). The IPR table will be available in this deliverable and also in the following online document:
https://docs.google.com/spreadsheets/d/1rqEX1bpSVL1xvlmwx8hMYZH2LwIarHY-b0NoefjwoeE/edit#gid=328286524

Licensing and Commercialization: Defining procedures for licensing and commercializing intellectual property beyond the project's lifespan, including negotiating agreements with external entities. At the stage of project finalization part of the results (see software asset chapter) are publicly available and others are available for demonstration upon request. For the cases of assets with unique ownership the owner will be responsible to prepare the agreement for licensing or / commercialization. In case of shared ownerships all the partners involved shall agree on the proposed license.
UPM team and UNIPV team will be responsible for the license preparation for the overall Capable system and also in this case this would require a previous agreement with the CAPABLE consortium in order to identify the fee for the maintenance of every component.

Enforcement Strategies: Outlining strategies and procedures for enforcing intellectual property rights, addressing any infringements or unauthorized use that may arise after the project concludes. For the case of CAPABLE, every partner will be able to request support to the legal department of each institution. The Coordinator (UNIPV) and WP8 leader (UPM) will support any enforcement related to the overall CAPABLE system.

Conclusions

This deliverable presented the final project's assets and the specific strategy of Intellectual Property management. These achievements have been described as software, datasets and knowledge assets. A proper strategy of monitoring, licensing and enforcing has been agreed at Consortium level and will grant the proper exploitation of the results of CAPABLE.